

5.0 REFERENCES

- Balls M, and Corcelle G. 1998a. Statement on the scientific validity of the rat skin transcutaneous electrical resistance (TER) test (an *in vitro* test for skin corrosivity). ATLA 26: 275-277.
- Balls M, and Corcelle G. 1998b. Statement on the scientific validity of the EPISKIN™ test (an *in vitro* test for skin corrosivity). ATLA 26: 278-280.
- Balls M, and Hellsten E. 2000. Statement on the Application of the EpiDerm human skin model for corrosivity testing. ATLA 28: 365-367.
- Barratt MD, Brantom PG, Fentem JH, Gerner I, Walker AP, and Worth AP. 1998. The ECVAM international validation study on *in vitro* test for skin corrosivity. 1. Selection and Distribution of the Test Chemicals. Toxicol In Vitro 12:471-482.
- Botham PA, Chamberlain M, Barratt MD, Curren RD, Esdaile DJ, Gardner JR., et al. 1995. A Prevalidation study on *in vitro* skin corrosivity testing: The Report and recommendations of ECVAM Workshop 6. ATLA 23:219-255.
- Botham PA, Hall TJ, Dennett R, McCall JC, Basketter DA, Whittle E, et al. 1992. The skin corrosivity test *in vitro*. Results of an inter-laboratory trial. Toxicol In Vitro 6:191-194.
- Cannon CL, Neal PJ, Southee JA, Kobilus J, and Klausner M. 1994. New epidermal model for dermal irritancy testing. Toxicol In Vitro 8: 889-891.
- DOT. 2002. Exemption DOT-E-10904 (Fifth Revision). Available: <http://hazmat.dot.gov/exemptions/E10904.pdf> [accessed 16 March 2004]
- DOT. 2003a. Shippers--General Requirements for Shipments and Packagings--Class 8 Definitions. 49 CFR 173.136. Available: http://www.access.gpo.gov/nara/cfr/waisidx_03/49cfr173_03.html [accessed 16 March 2004]
- DOT. 2003b. Shippers--General Requirements for Shipments and Packagings--Class 8 Assignment of Packing Group. 49 CFR 173.137. Available: http://www.access.gpo.gov/nara/cfr/waisidx_03/49cfr173_03.html [accessed 16 March 2004]
- ECVAM. 2001. Statement on the application of the CORROSITEX assay for skin corrosivity testing. 15th Meeting of European Centre for the Validation of Alternative Methods Scientific Advisory Committee (ESAC), Ispra, Italy. ATLA 29(2), 96-97.
- EPA. 1996. Method 1120, Dermal Corrosion. Washington, DC: U.S. Environmental Protection Agency. Available: <http://www.epa.gov/epaoswer/hazwaste/test/pdfs/1120.pdf> [accessed 16 March 2004].

EPA. 1998. Health Effects Test Guidelines: Acute Dermal Irritation. OPPTS 870.2500. Washington, DC. U.S. Environmental Protection Agency. Available: http://www.epa.gov/docs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-2500.pdf [accessed 16 March 2004].

Fentem JH, Archer GEB, Balls M, Botham PA, Curren RD, Earl LK, et al. 1998. The ECVAM international validation study on *in vitro* tests for skin corrosivity. 2. Results and evaluation by the management team. *Toxicol In Vitro* 12:483-524.

Fentem JH, Briggs D, Chesné C, Elliot GR, Harbell JW, Heylings JR., et al. 2001. A prevalidation study on *in vitro* tests for acute skin irritation: results and evaluation by the Management Team. *Toxicol In Vitro* 15:57-93.

Gordon VC, Harvell JD, and Maibach, HI. 1994. Dermal corrosion, the Corrositex® System: A DOT accepted method to predict corrosivity potential of test materials. In: *In vitro Skin Toxicology - Irritation, Phototoxicity, Sensitization. Alternative Methods in Toxicology*. Rougier A, Goldberg AM, Maibach, HI, eds. 10: 37-45. Mary Ann Liebert, New York.

ICCVAM. 1997. Validation and Regulatory Acceptance of Toxicological Test Methods. A Report of the *ad hoc* Interagency Coordinating Committee on the Validation of Alternative Methods. NIH Publication No. 97-3981. Research Triangle Park, NC. National Institute of Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/docs/guidelines/validate.pdf> [accessed 16 March 2004].

ICCVAM. 1999. Corrositex®: An *In Vitro* Test Method for Assessing Dermal Corrosivity Potential of Chemicals. NIH Publication No. 99-4495. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/docs/reports/corprrep.pdf> [accessed 16 March 2004].

ICCVAM. 2002. ICCVAM Evaluation of EPISKIN, EpiDerm (EPI-200), and the Rat Skin Transcutaneous Electrical Resistance (TER) Assay: *In vitro* Test Methods for Assessing Dermal Corrosivity Potential of Chemicals. NIH Publication No. 02-4502. Research Triangle Park, NC. National Institute of Environmental Health Sciences.

Available: <http://iccvam.niehs.nih.gov/methods/epiderm.htm> [accessed 16 March 2004].

ICCVAM. 2003. ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods. NIH Publication No. 03-4508. Research Triangle Park, NC. National Institute of Environmental Health Sciences.

Available: <http://iccvam.niehs.nih.gov/docs/guidelines/subguide.htm> [accessed 16 March 2004].

InVitro International. 1995. Corrositex Instruction Manual. Irvine, CA.
Available: <http://www.invitrointl.com/> [accessed 16 March 2004].

Liebsch, M, Traue, D, Barrabas, C, Spielmann, H, Uphill, P, Wilkins, S, et al. 2000. The ECVAM prevalidation study on the use of EpiDerm for skin corrosivity testing. ATLA 28:371-401.

Marshall, NJ, Goodwin, CJ, and Holt, SJ. 1995. A critical assessment of the use of microculture tetrazolium assays to measure cell growth and function. *Growth Regulation* 5:69-84.

OECD. 1996. Final Report of the OECD Workshop on Harmonisation of Validation and Acceptance Criteria for Alternative Toxicological Methods. (Solna Report) Paris: Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 16 March 2004].

OECD. 2002a. Report of the Stockholm Conference on Validation and Regulatory Acceptance of New and Updated Methods in Hazard Assessment. Paris: Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 16 March 2004].

OECD. 2002b. Test Guideline 404. OECD Guideline for Testing of Chemicals: Acute Dermal Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. Available: <http://www1.oecd.org/ehs/test/health.htm> [accessed 16 March 2004].

OECD. 2003a. OECD Guideline for the Testing of Chemicals: Draft Proposal for a New Guideline 431, *In Vitro* Skin Corrosion Human Skin Model System. OECD ENV/JM/TG(2002)8. Paris: Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 16 March 2004].

OECD. 2003b. OECD Guideline for the Testing of Chemicals: Draft Proposal for a New Guideline 430, *In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test (TER). Paris: Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 16 March 2004].

Oliver GJA, Pemberton MA, and Rhodes C. 1986. An *in vitro* skin corrosivity test-modifications and validation. *Fd Chem Toxicol* 24:507-512.

Oliver GJA, Pemberton MA, and Rhodes C. 1988. An *in vitro* model for identifying skin corrosive chemicals. I. Initial validation. *Toxicol In Vitro* 2: 7-17.

Parenteau NL, Bilbo P, Nolte CJ, Mason VS, and Rosenberg M. 1992. The organotypic culture of human skin keratinocytes and fibroblasts to achieve form and function. *Cytotechnology* 9:163-171.

Ponec M, Boelsma E, Weerheim A, Mulder A, Bouwstra J, and Mommaas, M. 2000. Lipid and ultrastructural characterization of reconstructed skin models. *Intl J Pharmaceutics* 203:211-225.

UN. 2003. Globally Harmonized System of Classification and Labeling of Chemicals (GHS). [ST/ SG/AC.10/30]. United Nations, New York and Geneva. Available: <http://www.unece.org/trans/danger/publi/ghs/officialtext.html> [accessed 16 March 2004]

UN. 2003b. Recommendations on the Transport of Dangerous Goods. Model Regulations. Thirteenth Revised Edition. United Nations, New York and Geneva. Available: http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html [accessed 16 March 2004]

Wilkins LM, Watson SR, Prosky SJ, Meunier, SF, and Parenteau, NL. 1994. Development of a bilayered living skin construct for clinical applications. Biotechnology and Bioengineering 43: 747-756.

Worth AP, Fentem JA, Balls M, Botham PA, Curren RD, Earl LK, et al. 1998. An evaluation of the proposed OECD testing strategy for skin corrosion. ATLA 26: 709-721.